



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/833,169 | 04/11/2001 | Andrew G. Lee | PC10636ATMC | 1529 |

7590 01/06/2006

Gregg C. Benson
Pfizer Inc.
Patent Department, MS 4159
Eastern Point Road
Groton, CT 06340

EXAMINER

WEBMAN, EDWARD J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/833,169 | LEE ET AL. | |
| | Examiner | Art Unit | |
| | Edward J. Webman | 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 10-12 and 40-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10, 11 and 46-48 is/are allowed.
- 6) ☒ Claim(s) 1-5 and 40-45, 50-51 is/are rejected.
- 7) ☒ Claim(s) 49, 52 and 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1616

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1, 2, 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Place et al.

Place et al teach a composition for treating sexual dysfunction. Estrogen antagonists including tamoxifen, raloxifene, centchroman, and droloxifene are disclosed (column 8 lines 27-35, 49-53).

Applicants argue that the “consisting of” language in claim1 overcomes the reference. However, that language limits the steps to those recited. However, it does not limit the composition.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4, 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Place et al.

Place et al is discussed above. As to the particular claimed compounds, applicants disclose them all as SERMS, synonymous with the older terminology "estrogen antagonist" (Halonen et al col. 1 lines 40-42).

It would have been obvious to one of ordinary skill to use the claimed compounds in the method of Place et al in view of their known function as estrogen agonists/antagonists as stipulated by applicants. No criticality has been shown for any particular compound, In re Boesch USPQ 215 (CCPA 1980).

Claims 5, 45, 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Place et al in view of Chiu et al.

Place et al is discussed above. As to the particular claimed compound, namely lasofoxifene, applicants disclose it as a SERM, synonymous with the older terminology "estrogen antagonist" (Halonen et al col. 1 lines 40-42).

It would have been obvious to one of ordinary skill to use the claimed compound in the method of Place et al in view of their known function as an estrogen agonists/antagonist as stipulated by applicants. No criticality has been shown for any particular compound, In re Boesch USPQ 215 (CCPA 1980). As to the claimed tartrate, Chiu et al teach the tartrate as a means of isolating the (-) optical isomer (abstract, column 1 line 66-column 2 line 8). Thus, it would have been further obvious to one of ordinary skill to use the tartrate salt, because the (-) optical isomer is isolated as the tartrate. As to the claimed pre and post-menopausal administration, it is well-known, even to the layman, that female sexual dysfunction may occur at any age, thus, one of

Art Unit: 1616

ordinary skill would recognize the obvious method as applicable to the claimed subjects.

Claims 1-5, 40-45, 50-51 are rejected. Claims 10-11, 46-48 are allowed. Claims 49, 52-53 are objected to as dependent on a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500